

4. Subject to paragraph 3, when a product is subject to a system of marketing approval in the territory of a Party in accordance with paragraph 1 or 2 and is also covered by a patent in that territory, the Party may not alter the term of protection that it provides in accordance with those paragraphs in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in those paragraphs.

5. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:

- (a) provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and
- (b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use.

ARTICLE 18.10: ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

General Obligations

1. Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights be in writing and state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based. Each Party shall also provide that those decisions and rulings be published²⁵ or, where publication is not practicable, otherwise made available to the public, in its national language in such a manner as to enable governments and right holders to become acquainted with them.

2. Each Party shall publicize information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative, and criminal systems, including any statistical information that the Party may collect for such purposes.²⁶

²⁵ A Party may satisfy the publication requirement in paragraph 1 by making the decision or ruling available to the public on the Internet.

²⁶ For greater certainty, nothing in paragraph 2 is intended to prescribe the type, format, and method of publication of the information a Party must publicize.

3. In civil, administrative, and criminal proceedings involving copyright or related rights, each Party shall provide for a presumption that, in the absence of proof to the contrary, the person whose name is indicated as the author, producer, performer, or publisher of the work, performance, or phonogram in the usual manner is the designated right holder in such work, performance, or phonogram. Each Party shall also provide for a presumption that, in the absence of proof to the contrary, the copyright or related right subsists in such subject matter. In civil, administrative, and criminal proceedings involving trademarks, each Party shall provide for a rebuttable presumption that a registered trademark is valid. In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.

Civil and Administrative Procedures and Remedies

4. Each Party shall make available to right holders²⁷ civil judicial procedures concerning the enforcement of any intellectual property right.

5. Each Party shall provide that:

- (a) in civil judicial proceedings, its judicial authorities shall have the authority to order the infringer to pay the right holder:
 - (i) damages adequate to compensate for the injury the right holder has suffered as a result of the infringement;²⁸ or
 - (ii) at least in the case of copyright or related rights infringement and trademark counterfeiting, the profits of the infringer that are attributable to the infringement, which may be presumed to be the amount of damages referred to in clause (i); and
- (b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, the value of the infringed good or service, measured by the market price, the suggested retail price, or other legitimate measure of value submitted by the right holder.

6. In civil judicial proceedings, each Party shall, at least with respect to works, phonograms, and performances protected by copyright or related rights, and in cases of trademark counterfeiting, establish or maintain pre-established damages, which shall be available on the election of the right holder. Pre-established damages shall be in an

²⁷ For purposes of Article 18.10, “right holder” includes a federation or an association having the legal standing and authority to assert such rights, and also includes a person that exclusively has any one or more of the intellectual property rights encompassed in a given intellectual property.

²⁸ In the case of patent infringement, damages adequate to compensate for the infringement shall not be less than a reasonable royalty.

amount sufficient to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement.²⁹

7. Each Party shall provide that its judicial authorities, except in exceptional circumstances, shall have the authority to order, at the conclusion of civil judicial proceedings concerning copyright or related rights infringement, patent infringement, or trademark infringement, that the prevailing party shall be awarded payment by the losing party of court costs or fees and, at least in proceedings concerning copyright or related rights infringement or willful trademark counterfeiting, reasonable attorney's fees. Further, each Party shall provide that its judicial authorities, at least in exceptional circumstances, shall have the authority to order, at the conclusion of civil judicial proceedings concerning patent infringement, that the prevailing party shall be awarded payment by the losing party of reasonable attorneys' fees.

8. In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities shall have the authority to order the seizure of allegedly infringing goods, materials, and implements relevant to the act of infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

9. Each Party shall provide that:

- (a) in civil judicial proceedings, at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional circumstances;
- (b) its judicial authorities shall have the authority to order that materials and implements that have been used in the manufacture or creation of such pirated or counterfeit goods be, without compensation of any sort, promptly destroyed or, in exceptional circumstances, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements; and
- (c) in regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.

10. Each Party shall provide that in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities shall have the authority to order the infringer to provide, for the purpose of collecting evidence, any information that the infringer possesses or controls regarding any person or persons involved in any aspect of the infringement and regarding the means of production or distribution channel of

²⁹ Neither Party is required to apply paragraph 6 to actions for infringement against a Party or a third party acting with the authorization or consent of a Party.

such goods or services, including the identification of third persons involved in the production and distribution of the infringing goods or services or in their channels of distribution, and to provide this information to the right holder or the judicial authorities.

11. Each Party shall provide that its judicial authorities have the authority to:

- (a) fine, detain, or imprison, in appropriate cases, a party to a civil judicial proceeding who fails to abide by valid orders issued by such authorities; and
- (b) impose sanctions on parties to a civil judicial proceeding, their counsel, experts, or other persons subject to the court's jurisdiction, for violation of judicial orders regarding the protection of confidential information produced or exchanged in a proceeding.

12. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that such procedures conform to principles equivalent in substance to those set out in this Chapter.

13. In civil judicial proceedings concerning the acts described in paragraphs 7 and 8 of Article 18.4, each Party shall provide that its judicial authorities shall, at the least, have the authority to:

- (a) impose provisional measures, including seizure of devices and products suspected of being involved in the prohibited activity;
- (b) provide an opportunity for the right holder to elect award of either actual damages it suffered or pre-established damages;
- (c) order payment to the prevailing right holder at the conclusion of civil judicial proceedings of court costs and fees, and reasonable attorney's fees, by the party engaged in the prohibited conduct; and
- (d) order the destruction of devices and products found to be involved in the prohibited activity.

Neither Party may make damages available under this paragraph against a nonprofit library, archives, educational institution, or public noncommercial broadcasting entity that sustains the burden of proving that it was not aware and had no reason to believe that its acts constituted a prohibited activity.

14. In civil judicial proceedings concerning the enforcement of intellectual property rights, each Party shall provide that its judicial authorities shall have the authority to order a party to desist from an infringement, in order, *inter alia*, to prevent infringing imports from entering the channels of commerce and to prevent their exportation.

15. In the event that a Party's judicial or other competent authorities appoint technical or other experts in civil proceedings concerning the enforcement of intellectual property rights and require that the parties to the litigation bear the costs of such experts, the Party should seek to ensure that such costs are closely related, *inter alia*, to the quantity and nature of work to be performed and do not unreasonably deter recourse to such proceedings.

Alternative Dispute Resolution

16. Each Party may permit use of alternative dispute resolution procedures to resolve civil disputes concerning intellectual property rights.

Provisional Measures

17. Each Party shall act on requests for provisional measures *inaudita altera parte* expeditiously.

18. Each Party shall provide that its judicial authorities have the authority to require the plaintiff, with respect to provisional measures, to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the plaintiff's right is being infringed or that such infringement is imminent, and to order the plaintiff to provide a reasonable security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse, and so as not to unreasonably deter recourse to such procedures.

Special Requirements Related to Border Measures

19. Each Party shall provide that any right holder initiating procedures for its competent authorities to suspend release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods³⁰ into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide sufficient information shall not

³⁰ For purposes of paragraphs 19 through 25:

(a) **counterfeit trademark goods** means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country of importation; and

(b) **pirated copyright goods** means any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and that are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

unreasonably deter recourse to these procedures. Each Party shall provide that the application to suspend the release of goods shall apply to all points of entry to its territory and remain applicable for a period of not less than one year from the date of application, or the period that the good is protected by copyright or that the relevant trademark registration is valid, whichever is shorter.

20. Each Party shall provide that its competent authorities shall have the authority to require a right holder initiating procedures to suspend the release of suspected counterfeit or confusingly similar trademark goods, or pirated copyright goods, to provide a reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Each Party shall provide that the security or equivalent assurance shall not unreasonably deter recourse to these procedures. Each Party may provide that the security may be in the form of a bond conditioned to hold the importer or owner of the imported merchandise harmless from any loss or damage resulting from any suspension of the release of goods in the event the competent authorities determine that the article is not an infringing good. In no case shall an importer be permitted to post a bond or other security to obtain possession of suspected counterfeit or confusingly similar trademark goods, or of pirated copyright goods.

21. Where its competent authorities have seized goods that are counterfeit or pirated, a Party shall inform the right holder within 30 days of the seizure of the names and addresses of the consignor, importer, exporter, or consignee, and provide to the right holder a description of the merchandise, the quantity of the merchandise, and, if known, the country of origin of the merchandise.

22. Each Party shall provide that its competent authorities may initiate border measures *ex officio*³¹ with respect to imported, exported, or in-transit merchandise,³² or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.

23. Each Party shall provide that goods that have been suspended from release by its customs authorities, and that have been forfeited as pirated or counterfeit, shall be destroyed, except in exceptional circumstances. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized, except in exceptional circumstances, to permit the exportation of counterfeit or pirated goods or to permit such goods to be subject to other customs procedures.

³¹ For greater certainty, the Parties understand that *ex officio* action does not require a formal complaint from a private party or right holder.

³² For purposes of paragraph 22, **in-transit merchandise** means goods under “Customs transit” and goods “transshipped,” as defined in the *International Convention on the Simplification and Harmonization of Customs Procedures* (Kyoto Convention).

24. Where an application fee or merchandise storage fee is assessed in connection with border measures to enforce an intellectual property right, each Party shall provide that the fee shall not be set at an amount that unreasonably deters recourse to these measures.

25. Each Party shall provide the other Party, on mutually agreed terms, with technical advice on the enforcement of border measures concerning intellectual property rights, and the Parties shall promote bilateral and regional cooperation on these matters.

Criminal Procedures and Remedies

26. Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Willful copyright or related rights piracy on a commercial scale includes:

- (a) significant willful copyright or related rights infringements that have no direct or indirect motivation of financial gain; and
- (b) willful infringements for purposes of commercial advantage or private financial gain.³³

Each Party shall treat willful importation or exportation of counterfeit or pirated goods as unlawful activities subject to criminal penalties.³⁴

27. Further to paragraph 26, each Party shall provide:

- (a) penalties that include sentences of imprisonment as well as monetary fines sufficient to provide a deterrent to future infringements, consistent with a policy of removing the infringer's monetary incentive. Each Party shall further encourage judicial authorities to impose those penalties at levels sufficient to provide a deterrent to future infringements, including the imposition of actual terms of imprisonment when criminal infringement occurs for purposes of commercial advantage or private financial gain;
- (b) that its judicial authorities shall have the authority to order the seizure of suspected counterfeit or pirated goods, any related materials and implements used in the commission of the offense, any documentary evidence relevant to the offense, and any assets traceable to the infringing activity. Each Party shall provide that such orders need not individually

³³ For purposes of paragraph 26 and Articles 18.4.7(a), 18.4.8(a), and 18.10.27 and for greater certainty, "financial gain" includes the receipt or expectation of anything of value.

³⁴ A Party may comply with the obligation in paragraph 26 in relation to exportation of pirated goods through its measures concerning distribution.

identify the items that are subject to seizure, so long as they fall within general categories specified in the order;

- (c) that its judicial authorities shall have the authority to order, among other measures, the forfeiture of any assets traceable to the infringing activity;
- (d) that its judicial authorities shall, except in exceptional cases, order
 - (i) the forfeiture and destruction of all counterfeit or pirated goods, and any articles consisting of a counterfeit mark; and
 - (ii) the forfeiture and/or destruction of materials and implements that have been used in the creation of pirated or counterfeit goods.

Each Party shall further provide that forfeiture and destruction under this subparagraph and subparagraph (c) shall occur without compensation of any kind to the defendant;

- (e) that, in criminal cases, its judicial or other competent authorities shall keep an inventory of goods and other material proposed to be destroyed, and shall have the authority temporarily to exempt these materials from the destruction order to facilitate the preservation of evidence on notice by the right holder that it wishes to bring a civil or administrative case for damages; and
- (f) that its authorities may initiate legal action *ex officio* with respect to the offenses described in this Chapter, without the need for a formal complaint by a private party or right holder.

28. Each Party shall also provide for criminal procedures and penalties to be applied, even absent willful trademark counterfeiting or copyright piracy, at least in cases of knowing trafficking in:

- (a) counterfeit labels or illicit labels affixed to, enclosing, or accompanying, or designed to be affixed to, enclose, or accompany: a phonogram, a copy of a computer program or other literary work, a copy of a motion picture or other audiovisual work, or documentation or packaging for such items; and
- (b) counterfeit documentation or packaging for items of the type described in subparagraph (a).

29. Each Party shall also provide for criminal procedures to be applied against any person who, without authorization of the holder of copyright or related rights in a motion picture or other audiovisual work, knowingly uses or attempts to use an audiovisual recording device to transmit or make a copy of the motion picture or other audiovisual

work, or any part thereof, from a performance of the motion picture or other audiovisual work in a public motion picture exhibition facility.

Liability for Service Providers and Limitations

30. For the purpose of providing enforcement procedures that permit effective action against any act of copyright infringement covered by this Chapter, including expeditious remedies to prevent infringements and criminal and civil remedies that constitute a deterrent to further infringements, each Party shall provide, consistent with the framework set out in this Article:

- (a) legal incentives for service providers to cooperate with copyright³⁵ owners in deterring the unauthorized storage and transmission of copyrighted materials; and
- (b) limitations in its law regarding the scope of remedies available against service providers for copyright infringements that they do not control, initiate, or direct, and that take place through systems or networks controlled or operated by them or on their behalf, as set forth in this subparagraph (b).³⁶
 - (i) These limitations shall preclude monetary relief and provide reasonable restrictions on court-ordered relief to compel or restrain certain actions for the following functions, and shall be confined to those functions:³⁷
 - (A) transmitting, routing, or providing connections for material without modification of its content, or the intermediate and transient storage of such material in the course thereof;
 - (B) caching carried out through an automatic process;
 - (C) storage at the direction of a user of material residing on a system or network controlled or operated by or for the service provider; and
 - (D) referring or linking users to an online location by using information location tools, including hyperlinks and directories.

³⁵ For purposes of paragraph 30, “copyright” includes related rights.

³⁶ Subparagraph (b) is without prejudice to the availability of defenses to copyright infringement that are of general applicability.

³⁷ Either Party may request consultations with the other Party to consider how to address under subparagraph (b) functions of a similar nature that a Party identifies after the date this Agreement enters into force.

- (ii) These limitations shall apply only where the service provider does not initiate the chain of transmission of the material, and does not select the material or its recipients (except to the extent that a function described in clause (i)(D) in itself entails some form of selection).
- (iii) Qualification by a service provider for the limitations as to each function in clauses (i)(A) through (D) shall be considered separately from qualification for the limitations as to each other function, in accordance with the conditions for qualification set forth in clauses (iv) through (vii).
- (iv) With respect to functions referred to in clause (i)(B), the limitations shall be conditioned on the service provider:
 - (A) permitting access to cached material in significant part only to users of its system or network who have met conditions on user access to that material;
 - (B) complying with rules concerning the refreshing, reloading, or other updating of the cached material when specified by the person making the material available online in accordance with a generally accepted industry standard data communications protocol for the system or network through which that person makes the material available;
 - (C) not interfering with technology consistent with industry standards accepted in the Party's territory used at the originating site to obtain information about the use of the material, and not modifying its content in transmission to subsequent users; and
 - (D) expeditiously removing or disabling access, on receipt of an effective notification of claimed infringement, to cached material that has been removed or access to which has been disabled at the originating site.
- (v) With respect to functions referred to in clauses (i)(C) and (D), the limitations shall be conditioned on the service provider:
 - (A) not receiving a financial benefit directly attributable to the infringing activity, in circumstances where it has the right and ability to control such activity;

- (B) expeditiously removing or disabling access to the material residing on its system or network on obtaining actual knowledge of the infringement or becoming aware of facts or circumstances from which the infringement was apparent, such as through effective notifications of claimed infringement in accordance with clause (ix); and
 - (C) publicly designating a representative to receive such notifications.
- (vi) Eligibility for the limitations in this subparagraph shall be conditioned on the service provider:
 - (A) adopting and reasonably implementing a policy that provides for termination in appropriate circumstances of the accounts of repeat infringers; and
 - (B) accommodating and not interfering with standard technical measures accepted in the Party's territory that protect and identify copyrighted material, that are developed through an open, voluntary process by a broad consensus of copyright owners and service providers, that are available on reasonable and nondiscriminatory terms, and that do not impose substantial costs on service providers or substantial burdens on their systems or networks.
- (vii) Eligibility for the limitations in this subparagraph may not be conditioned on the service provider monitoring its service, or affirmatively seeking facts indicating infringing activity, except to the extent consistent with such technical measures.
- (viii) If the service provider qualifies for the limitations with respect to the function referred to in clause (i)(A), court-ordered relief to compel or restrain certain actions shall be limited to terminating specified accounts, or to taking reasonable steps to block access to a specific, non-domestic online location. If the service provider qualifies for the limitations with respect to any other function in clause (i), court-ordered relief to compel or restrain certain actions shall be limited to removing or disabling access to the infringing material, terminating specified accounts, and other remedies that a court may find necessary, provided that such other remedies are the least burdensome to the service provider among comparably effective forms of relief. Each Party shall provide that any such relief shall be issued with due regard for the relative burden to the service provider and harm to the copyright owner, the technical feasibility and effectiveness of the remedy and whether less burdensome,

comparably effective enforcement methods are available. Except for orders ensuring the preservation of evidence, or other orders having no material adverse effect on the operation of the service provider's communications network, each Party shall provide that such relief shall be available only where the service provider has received notice of the court order proceedings referred to in this subparagraph and an opportunity to appear before the judicial authority.

- (ix) For purposes of the notice and take down process for the functions referred to in clauses (i)(C) and (D), each Party shall establish appropriate procedures in its law or in regulations for effective notifications of claimed infringement, and effective counter-notifications by those whose material is removed or disabled through mistake or misidentification. Each Party shall also provide for monetary remedies against any person who makes a knowing material misrepresentation in a notification or counter-notification that causes injury to any interested party as a result of a service provider relying on the misrepresentation.
- (x) If the service provider removes or disables access to material in good faith based on claimed or apparent infringement, each Party shall provide that the service provider shall be exempted from liability for any resulting claims, provided that, in the case of material residing on its system or network, it takes reasonable steps promptly to notify the person making the material available on its system or network that it has done so and, if such person makes an effective counter-notification and is subject to jurisdiction in an infringement suit, to restore the material online unless the person giving the original effective notification seeks judicial relief within a reasonable time.
- (xi) Each Party shall establish an administrative or judicial procedure enabling copyright owners who have given effective notification of claimed infringement to obtain expeditiously from a service provider information in its possession identifying the alleged infringer.
- (xii) For purposes of the function referred to in clause (i)(A), **service provider** means a provider of transmission, routing, or connections for digital online communications without modification of their content between or among points specified by the user of material of the user's choosing, and for purposes of the functions referred to in clauses (i)(B) through (D) **service provider** means a provider or operator of facilities for online services or network access.